REMARKS

STATUS OF THE CLAIMS

Claims 1-3 and 7-20 were pending in this application, claims 1-3 and 17-20 were previously withdrawn. Claims 7, 9, 10, and 12 have been amended herein. Following entry of the amendments claims 7-16 will be pending and at issue.

SUPPORT FOR AMENDMENTS TO THE CLAIMS

Claim 7 has been amended to include the term "a PCR assay." Support for the amendment can be found throughout the specification as filed, e.g., original claim 8, paragraphs [00017] through [00019], and paragraph [00021].

Claims 7, 9, 10, and 12 have been amended to use the language "consisting of." Support for the amendment can be found throughout the specification as filed, e.g., the sequence listing.

The amendments to the claims therefore add no new matter and entry is respectfully requested.

SUPPORT FOR AMENDMENTS TO THE SPECIFICATION

The specification has been amended at paragraph [00011] to merely delete reference to an embedded hyperlink. The amendments therefore add no new matter and entry is respectfully requested.

OBJECTION TO THE SPECIFICATION

The disclosure was objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant has deleted the embedded hyperlink and/or other form of browser-executable code and withdrawal of the rejection is requested.

REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The claims were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

In the Office Action, the Examiner stated:

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, "using an assay to detect an amplicon comprising SEQ ID NO: 4 or 8" alone is insufficient to describe the genus.

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Applicants claims fail to disclose how amplicons comprising SEQ ID NO: 4 or SEQ ID NO: 8 are generated. Detecting such sequences within a sample is routine in the art, however generating such amplicons in the first place requires knowledge of the specific primers and probes used to amplify the particular sequences. Without disclosure of the particular primers and probes to generate the amplicon, Applicants' written description requirement is not deemed to be fulfilled. Furthermore, Applicants have disclosed the precise amplicon represented by SEQ ID NO: 4, SEQ ID NO: 8, SEQ ID NO: 12, SEQ ID NO: 16, SEQ ID NO: 20, SEQ ID NO: 24, SEQ ID NO: 28 and SEQ ID NO: 32, in other words "consisting of" the identified amplicon. Applicants disclosure fails to identify the upstream or downstream regions of this fragment, which will have a profound impact on the activity of the molecule. Accordingly, the written description of the amplicon is sufficient only for the identified fragment, i.e., "consisting of." It is noted that Applicants withdrawn claims do set forth of the specific primers and probes used to generate the Amplicon of SEQ ID NO: 4 and 8. However, the written description requirement for these probes is also only satisfied for the described probe, i.e., consisting of. Additional nucleotides on either side of the identified probe will dramatically alter its binding interaction with other DNA molecules.

Without agreeing with the Examiner's rejection but to expedite prosecution of this application, Applicant has amended claim 7 to change "an assay" to "a PCR assay." In addition, Applicant has amended claims 7, 9, 10, and 12 to recite "...consisting of SEQ ID NO: ..."

The claims as amended are drawn to methods for detection of Francisella tularensis in a sample using PCR assays to detect Francisella tularensis nucleic acids (amplicons) consisting of SEQ ID NO:4 and SEQ ID NO:8 (claim 7) and to detect nucleic acids (amplicons) consisting of SEQ ID NO:4, SEQ ID NO:8, SEQ ID NO:12, SEQ ID NO:16, SEQ ID NO:20, SEQ ID NO:24, SEQ ID NO:28 and SEQ ID NO:32.

The specification clearly provides written description support for using PCR assays to detect the recited nucleic acids (amplicons) at, e.g., paragraphs [00017] through [00019]. One

example of how to run such an assay is provided at paragraph [00021]. The sequence listing combined with the "Brief Description of the Sequences" beginning on page 4 provides written description of one example of primer/probe sets for use in a PCR assay for detection of the recited nucleic acids (amplicons). Results using the primer/probe sets recited in claims 9 and 12, e.g., primers SEQ ID NO:1 and SEQ ID NO:2 together with probe SEQ ID NO:3 to detect nucleic acid (amplicon) SEQ ID NO:4, are shown in Table 1.

Applicant respectfully requests withdrawal of this rejection as drawn to the amended claims.

CONCLUSION

Entry of the amendments and examination of the claims is respectfully requested, and a notice of allowance is earnestly solicited. If the Examiner has any questions concerning this Response, the Examiner is invited to telephone Applicant's representative at (415) 875-2316.

Respectfully submitted,
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